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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,685	11/15/2001	Menashe Shahar	P-3439-US	7189
7590	07/02/2004		EXAMINER	
Browdy And Neimark 624 Ninth Street, N. W. Washington, DC 20001			SHAW, SHAWNA JEANNINE	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/987,685	SHAHAR ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Shawna J. Shaw	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 April 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 3,5-32 and 44-46 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 3,5-32 and 44-46 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 15 November 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>03242004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 3, 5, 13-22 and 25-32 have been considered but are moot in view of the new ground(s) of rejection.
2. The indicated allowability of claims 6-12, 23 and 24 is withdrawn in view of the newly discovered reference(s) to MacKinnon et al. and Handa. Rejections based on the newly cited reference(s) follow.

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the processing unit comprising the spectral analytical instrument producing an analog signal (claim 1) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to

show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

4. Claim 3 is objected to because of the following informalities: In claim 3 line 4, "said ear" should be –the ear--. In line 4 of claims 23 and 24, "the processing unit further compares" should be changed to –the processing unit is configured to compare—to avoid functional intended use. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 5, 6, 9-15, 29-32 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by Sheehan et al. of record or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheehan et al. in view of MacKinnon et al.

Regarding claims 3, 5, 6, 9-15, 29-32 and 44, Sheehan et al. teaches a portable otoscope including a device capable of obtaining a spectrum of reflected light (i.e., CCD, col. 5 lines 25-34 – which may also act as a spectral analytical instrument as evidenced by 4,793,675 col. 2 lines 1-5), and a microprocessor with accessible memory (208, 210 – inherently processing digitized signals) capable of translating the spectrum of reflected light to one or more output values related to the condition of the ear and for comparing with a reference value stored in memory or available via the Internet (col. 6 line 46 – col. 7 line 29). Sheehan further discloses a lamp (205), a light fiber, a user interface (212) and a LCD display (220). Sheehan et al. differs from the claimed invention in that a

spectral analytical instrument embodied as a filter is not addressed explicitly. MacKinnon et al. generally teach the use of spectral filters in endoscopes, otoscopes, etc. to reduce the need for bulky sensor arrays, analyzers etc. (col. 2 lines 20-24, col. 12 lines 31-48) and to optimize diagnosis (col. 7 line 65 – col. 8 line 7). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to modify the device of Sheehan et al. to include detection filters/analyzers as taught by MacKinnon et al. to provide a compact and inexpensive means for enhancing and optimizing diagnosis.

6. Claims 18-22 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan et al. or Sheehan et al. in view of MacKinnon et al. as applied to claim 6 above.

Further regarding claims 18-22, although Sheehan et al. makes a comparison to previously acquired measurements, comparison to a healthy ear, the other ear, or ears with otitis media is not addressed expressly. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to compare with a healthy ear, the other ear, or ears with otitis media because Applicant has not disclosed that such comparisons provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with reference data about the patient, or another, stored in a database or on the Internet as taught by Sheehan et al. since many reference values may be obtained therefrom providing indication for a variety of ear-related disorders.

Further regarding claims 25-28, although Sheehan et al. teaches an LCD display and input buttons (216) or menu-control system (col. 5 lines 1, 2), a numeric keyboard is not addressed expressly. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a numeric keyboard because Applicant has not disclosed that a numeric keypad provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either input buttons, menu-control input or a numeric keyboard because all perform the same function of allowing a user to input information into a patient file.

7. Claims 16, 17, 23, 24, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan et al. of record, or Sheehan et al. in view of MacKinnon et al., and further in view of Mahler et al. of record.

Regarding claims 16, 17, 23, 24, 45 and 46, although Sheehan et al. obtains infrared ear measurements over time, and more specifically temperature measurements and fluid identification (col. 6 line 66 – col. 7 line 3), Sheehan et al. differs from the claimed invention in that the steps of specifically diagnosing otitis media or degree of redness or effusion are not discussed. Mahler et al. generally teaches a computerized process for comparing acquired temperature measurements over time with a pre-determined reference to diagnose otitis media and to quantify the extent of associated redness and effusion (col. 1 lines 25-33 and 60-65, col. 2 lines 5-7, fig. 3). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to further modify

the microprocessor of Sheehan et al. to compare the acquired temperature data with a pre-determined reference to diagnose conditions such as otitis media as taught by Mahler et al. so as to provide a more cost effective diagnostic tool rendering diagnoses related to the condition of the ear with improved accuracy.

***Allowable Subject Matter***

8. Claims 7 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schulze et al. (5,673,692) and Suszynski et al. (Re. 34,599) teach the use of thermistors and infrared sensors as functional equivalents to achieve the same result, see col. 8 lines 36-40 and col. 1 lines 19-22, respectively.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw  
Primary Examiner  
06/17/2004